1 2 3 4 5 6 7	John B. Sganga, Jr. (SBN 116,211) john.sganga@knobbe.com Craig S. Summers (SBN 108,688) craig.summers@knobbe.com Christy G. Lea (SBN 212,060) christy.lea@knobbe.com Joshua J. Stowell (SBN 246,916) joshua.stowell@knobbe.com KNOBBE, MARTENS, OLSON & B 2040 Main Street, 14th Floor Irvine, CA 92614 Telephone: 949-760-0404 Facsimile: 949-760-9502	EAR, LLP
8 9 10	Hans L. Mayer (SBN 291,998) hans.mayer@knobbe.com 1925 Century Park East, Suite 600 Los Angeles, CA 90067 Telephone: 310-551-3450	
11 12 13	Attorneys for Plaintiffs EDWARDS LIFESCIENCES CORPO EDWARDS LIFESCIENCES LLC	ORATION and
14 15 16 17		ATES DISTRICT COURT DISTRICT OF CALIFORNIA
18 19 20 21 22	EDWARDS LIFESCIENCES CORPORATION, a Delaware corporation, and EDWARDS LIFESCIENCES LLC, a Delaware corporation  Plaintiff,  v.	Case No. 8:19-cv-345 COMPLAINT FOR PATENT INFRINGEMENT DEMAND FOR JURY TRIAL
<ul> <li>23</li> <li>24</li> <li>25</li> <li>26</li> <li>27</li> </ul>	ABBOTT CARDIOVASCULAR SYSTEMS, INC., a California corporation,  Defendant.	

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Plaintiffs Edwards Lifesciences Corporation and Edwards Lifesciences LLC, for their complaint against Defendant Abbott Cardiovascular Systems, Inc., allege as follows:

#### I. THE PARTIES

- 1. Plaintiff Edwards Lifesciences Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Edwards Way, Irvine, California 92614.
- 2. Plaintiff Edwards Lifesciences LLC is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Edwards Way, Irvine, California 92614.
- 3. Defendant Abbott Cardiovascular Systems, Inc. is a corporation organized and existing under the laws of the State of California, with its principal place of business at 3200 Lakeside Drive, Santa Clara, California 95054.
- 4. Edwards Lifesciences Corporation and Edwards Lifesciences LLC shall be collectively referred to herein as "Plaintiffs" or "Edwards Lifesciences." Abbott Cardiovascular Systems, Inc. shall be referred to herein as "Defendant" or "ACS."

## II. JURISDICTION AND VENUE

- This is an action for patent infringement arising under the patent 5. laws of the United States of America, Title 35, United States Code. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 6. Defendant is engaged in the business of manufacturing, selling, offering for sale, and/or importing mitral valve repair devices sold under the names MitraClip, MitraClip NT, MitraClip NTR, and MitraClip XTR (collectively, the "Accused Products") in the United States, including within this District.

- 7. Venue is proper in this District pursuant to 28 U.S.C. § 1400(b), because the Defendant has committed acts of infringement in this District and because the Defendant has several established places of business in this district, including in Temecula, California.
- 8. This Court has personal jurisdiction over Defendant. The Defendant has committed acts of infringement in this District, including manufacturing, selling, offering for sale, and/or importing the Accused Products in this District.

#### III. THE PATENTS-IN-SUIT

- 9. On April 13, 2004, the United States Patent and Trademark Office issued United States Patent No. 6,719,767 ("the '767 Patent") entitled "Device and a Method for Treatment of Atrioventricular Regurgitation," a true and correct copy of which is attached as Exhibit 1.
- 10. Edwards Lifesciences Corporation is the assignee of all rights to the '767 Patent, including the right to sue for and recover all past and present damages for infringement of the '767 Patent. Edwards Lifesciences LLC is the exclusive licensee of the '767 Patent.
- 11. On March 14, 2006, the United States Patent and Trademark Office issued United States Patent No. 7,011,669 ("the '669 Patent") entitled "Device and a Method for Treatment of Atrioventricular Regurgitation," a true and correct copy of which is attached as Exhibit 2.
- 12. Edwards Lifesciences Corporation is the assignee of all rights to the '669 Patent, including the right to sue for and recover all past and present damages for infringement of the '669 Patent. Edwards Lifesciences LLC is the exclusive licensee of the '669 Patent.
- 13. On November 22, 2011, the United States Patent and Trademark Office issued United States Patent No. 8,062,313 ("the '313 Patent") entitled "Device and a Method for Treatment of Atrioventricular Regurgitation," a true

and correct copy of which is attached as Exhibit 3.

- 14. Edwards Lifesciences Corporation is the assignee of all rights to the '313 Patent, including the right to sue for and recover all past and present damages for infringement of the '313 Patent. Edwards Lifesciences LLC is the exclusive licensee of the '313 Patent.
- 15. The '767 Patent, the '669 Patent, and the '313 Patent are collectively referred to herein as the Asserted Patents.

#### IV. COUNT 1 – INFRINGEMENT OF THE '767 PATENT

- 16. Edwards Lifesciences incorporates paragraphs 1 through 15 as though fully set forth herein.
- 17. Defendant has made, used, sold, and/or offered for sale the Accused Products in the United States, imported the Accused Products into the United States, and/or exported from the United States all or a substantial portion of the components of the Accused Products for which no substantial noninfringing use exists, including within this District.
- 18. Defendant has directly infringed at least Claim 14 of the '767 Patent either literally or under the doctrine of equivalents by manufacturing, selling, offering for sale, and/or importing the Accused Products, in violation of 35 U.S.C. § 271(a).
- 19. By way of example, and not limitation, Defendant's direct infringement of Claim 14 of the '767 Patent is shown in the claim chart in Exhibit 4, attached hereto and incorporated herein by reference, which compares exemplary Claim 14 to the Accused Products.
- 20. Each version of the MitraClip implant requires a clip delivery system, including a catheter, for implantation. The clip delivery system is especially made for use with the MitraClip. The MitraClip Instructions for Use instruct clinicians to use the clip delivery system to implant the MitraClip.
  - 21. Defendant has also infringed at least Claim 14 of the '767 Patent

by supplying or causing to be supplied from the United States all or a substantial portion of the components of the Accused Products, including the MitraClip implant and/or the clip delivery system, in such a manner as to actively induce the combination of the components outside the United States in a manner that would infringe if the combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1).

- 22. Defendant has also infringed at least Claim 14 of the '767 Patent by supplying components of the Accused Products, including the MitraClip and/or the clip delivery system, that are especially made or adapted for use in the Accused Products and are not a staple article or commodity of commerce suitable for substantial noninfringing use, with knowledge that the components are so made or adapted and intending that the components will be combined outside the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2).
- 23. Defendant had actual knowledge of the '767 Patent prior to the filing of this Complaint. For example, on September 22, 2004 during the prosecution of U.S. Patent No. 7,335,213, Defendant cited the '767 Patent in an information disclosure statement to the United States Patent and Trademark Office.
- 24. Edwards Lifesciences has been damaged by Defendant's infringing activities in an amount to be determined at trial, but in no event less than a reasonable royalty.

# V. COUNT 2 – INFRINGEMENT OF THE '669 PATENT

- 25. Edwards Lifesciences incorporates paragraphs 1 through 24 as though fully set forth herein.
- 26. Defendant has induced infringement of the '669 Patent under 35 U.S.C. § 271(b), by, for example, instructing clinicians to use the Accused

Products in a manner that constitutes direct infringement of the '669 Patent.

- 27. Defendant has also contributed to the infringement of the '669 Patent under 35 U.S.C. § 271(c) by, for example, offering for sale, selling, and/or importing the Accused Products for use in practicing the patented process of the '669 Patent, where the Accused Products constitute a material part of the invention, and are not a staple article or commodity of commerce suitable for substantial non-infringing use, and are known by Defendant to be especially adapted for use in an infringement of the '669 Patent. As a result, the Accused Products have been used by customers and clinicians in a manner that directly infringes at least claim 1 of the '669 Patent.
- 28. For example, in the MitraClip Instructions For Use (attached hereto as Exhibit 5), Defendant instructs clinicians to use the Accused Products in a manner that infringes, either literally or under the doctrine of equivalents, one or more claims of the '669 Patent, including at least Claim 1.
- 29. When clinicians perform the method of using the Accused Products, as described at least in Exhibit 5, they are directly infringing at least Claim 1 of the '669 Patent as described in the claim chart in Exhibit 6, attached hereto and incorporated herein by reference.
- 30. Defendant knew that clinicians would infringe the '669 Patent by using the Accused Products during the term of the '669 Patent. For example, Defendant provides Instructions for Use (Exhibit 5) to clinicians with the Accused Products. The Instructions for Use instruct the clinician to perform a method of using the Accused Products that would constitute direct infringement of at least Claim 1 of the '669 Patent. Defendant also knew that the Accused Products were not a staple article or commodity of commerce for substantial non-infringing use.
- 31. Defendant had the specific intent to induce and did induce clinicians to infringe the '669 Patent under 35 U.S.C. § 271(b), by, for example,

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causing clinicians to use the Accused Products in a manner that constitutes direct infringement of at least Claim 1 of the '669 Patent during the term of the '669 Patent, including by providing marketing materials and instructions for use, such as for example the Instructions for Use (Exhibit 5), to clinicians that instruct the clinicians to perform a method of using the Accused Products that infringes at least Claim 1 of the '669 Patent.

- 32. Defendant had actual knowledge of the '669 Patent prior to the filing of this Complaint. For example, on July 25, 2018 during the prosecution of U.S. Patent No. 10,188,392, Defendant cited the '669 Patent in an information disclosure statement to the United States Patent and Trademark Office.
- 33. Edwards Lifesciences has been damaged by Defendant's infringing activities in an amount to be determined at trial, but in no event less than a reasonable royalty.

### VI. COUNT 3 – INFRINGEMENT OF THE '313 PATENT

- 34. Edwards Lifesciences incorporates paragraphs 1 through 33 as though fully set forth herein.
- 35. Defendant has made, used, sold, and/or offered for sale the Accused Products in the United States, imported the Accused Products into the United States, and/or exported from the United States all or a substantial portion of the components of the Accused Products for which no substantial noninfringing use exists, including within this District.
- 36. Defendant has directly infringed at least Claim 1 of the '313 Patent either literally or under the doctrine of equivalents by manufacturing, selling, offering for sale, and/or importing the Accused Products, in violation of 35 U.S.C. § 271(a).
- 37. By way of example, and not limitation, Defendant's direct infringement of Claim 1 of the '313 Patent is shown in the claim chart in

Exhibit 7, attached hereto and incorporated herein by reference, which compares exemplary Claim 1 to the Accused Products.

- 38. Each version of the MitraClip implant requires a clip delivery system, including a catheter, for implantation. The clip delivery system is especially made for use with the MitraClip. The MitraClip Instructions for Use instruct clinicians to use the clip delivery system to implant the MitraClip.
- 39. Defendant has also infringed at least Claim 1 of the '313 Patent by supplying or causing to be supplied from the United States all or a substantial portion of the components of the Accused Products, including the MitraClip implant and/or the clip delivery system, in such a manner as to actively induce the combination of the components outside the United States in a manner that would infringe if the combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(1).
- 40. Defendant has also infringed at least Claim 1 of the '313 Patent by supplying components of the Accused Products, including the MitraClip and/or the clip delivery system, that are especially made or adapted for use in the Accused Products and are not a staple article or commodity of commerce suitable for substantial noninfringing use, with knowledge that the components are so made or adapted and intending that the components will be combined outside the United States in a manner that would infringe the patent if such combination occurred within the United States, in violation of 35 U.S.C. § 271(f)(2).
- 41. Defendant had actual knowledge of the patent application that issued as the '313 Patent prior to the filing of this Complaint. For example, on July 25, 2018, during the prosecution of U.S. Patent No. 10,188,392, Defendant cited the patent application that issued as the '313 Patent in an information disclosure statement to the United States Patent and Trademark Office. Defendant had actual knowledge of the '313 Patent prior to the filing of this

Complaint. Defendant is a sophisticated company that monitors the patents of its competitors and as a result of this monitoring learned that the '313 Patent issued from the patent application.

42. Edwards Lifesciences has been damaged by Defendant's infringing activities in an amount to be determined at trial, but in no event less than a reasonable royalty.

#### VII. PRAYER FOR RELIEF

WHEREFORE, Edwards Lifesciences requests the following relief:

- 43. A judgment in favor of Edwards Lifesciences that Defendant has infringed one or more claims of the '767 Patent;
- 44. A judgment in favor of Edwards Lifesciences that Defendant has induced others to infringe one or more claims of the '669 Patent;
- 45. A judgment in favor of Edwards Lifesciences that Defendant has contributed to the infringement by others of one or more claims of the '669 Patent;
- 46. A judgment in favor of Edwards Lifesciences that Defendant has infringed one or more claims of the '313 Patent;
- 47. A judgment in favor of Edwards Lifesciences that this case is exceptional under 35 U.S.C. § 285 and awarding Edwards Lifesciences its attorneys' fees;
- 48. A judgment and order requiring Defendant to pay Edwards Lifesciences damages adequate to compensate for infringement under 35 U.S.C. § 284, which damages in no event shall be less than a reasonable royalty for the use made of the inventions of the Asserted Patents, including supplemental damages for any continuing post-verdict infringement up until the entry of judgment, with an accounting, as needed, pre- and post-judgment interest and costs, including expenses and disbursements;
  - 49. A judgment in favor of Edwards Lifesciences, and against

1	Defendant, that interest, costs, and expenses be awarded in favor of Edwards		
2	Lifesciences; and		
3	50. Any and all such further necessary relief as the Court may deem		
4	just and proper.		
5		Respectfully submitted,	
6		KNOBBE, MARTENS, OLSON & BEAR, LLP	
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9	Dated: February 22, 2019	By: /s/ Joshua Stowell John B. Sganga, Jr.	
10		Craig S. Summers	
11		Christy G. Lea Joshua J. Stowell	
12		Hans L. Mayer	
13		Attorneys for Plaintiffs,	
14		EDWARDS LIFESCIENCES CORPORATION	
15		and EDWARDS LIFESCIENCES LLC	
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VIII. <u>DEMAND FOR TRIAL BY JURY</u> Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs Edwards Lifesciences Corporation and Edwards Lifesciences LLC hereby demand a trial by jury on all issues so triable. Respectfully submitted, KNOBBE, MARTENS, OLSON & BEAR, LLP Dated: February 22, 2019 By: /s/ Joshua Stowell John B. Sganga, Jr. Craig S. Summers Christy G. Lea Joshua J. Stowell Hans L. Mayer Attorneys for Plaintiff, EDWARDS LIFESCIENCES CORPORATION and EDWARDS LIFESCIENCES LLC